UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,358	11/20/2006	Ashfaque Hossain	CRE-102.1 US (8492/96340)	5617

24628 7590 04/01/2009

Husch Blackwell Sanders, LLP
Husch Blackwell Sanders LLP Welsh & Katz
120 S RIVERSIDE PLAZA
22ND FLOOR
CHICAGO, IL 60606

EXAMINER	
BABIC, CHRISTOPHER M	

ART UNIT	PAPER NUMBER
1637	

MAIL DATE	DELIVERY MODE
04/01/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,358	HOSSAIN ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER M. BABIC	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *15-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group I, claims 1-14, in the reply filed on December 19, 2008 is acknowledged. Thus, the restriction requirement is still deemed proper and hereby made FINAL. As such, claim(s) 15-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claim Interpretation

With regard to the term "lysis buffer," since the specification expressly defines the term as comprising a chelating agent and a dispersing agent (see pg. 15, para. 5, specification), the claimed method is interpreted to require the presence of such chemicals.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, and 5-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Mehra et al. (U.S. 5,777,099).

As an initial matter, Applicant is notified that the claimed method is recited in "comprising" language, which allows for the inclusion of outside steps.

Mehra teaches methods of RNA isolation from biological specimens (abstract; col. 5-6, for example). Specifically, the reference teaches methods (col. 5-6, Example 1, for example) comprising: (a) contacting the biological specimen with an admixture of (i) a mono-phasic solution of phenol and guanidine isothiocyanate (col. 5-6, Example 1, phenol phase of the lysis solution necessarily contains an amount of guanidine isothiocyanate, for example), and (ii) a lysis buffer under conditions and for a time appropriate to form a homogenate (col. 5-6, Example 1, non-phenol phase of the lysis solutions contains SDS and EDTA, for example); (b) admixing the homogenate with a water-immiscible organic solvent under conditions and for a time appropriate to form an aqueous phase and an organic phase (col. 5-6, Example 1, addition of chloroform, for example; (c) contacting the aqueous phase with a C_1-C_4 lower alcohol under conditions and for a time to form a precipitated RNA (col. 5-6, Example 1, isopropanol precipitation, or example); and (d) recovering the precipitated RNA (col. 5-6, Example 1, isolation of RNA pellet, or example).

With regard to the "mono-phasic" solution, it is noted that the majority of the guanidine compound is in the non-phenol phase of the lysis solution; however, the lysis solution made in Example 1 would necessarily contain an amount of guanidine reagent, as noted by the reference (col. 4; "The resulting composition is two-phase at or about ambient temperature with the upper phase being predominately phenol with at most

small amounts of other composition components"). Thus, Mehra technically teaches a mono-phasic solution of phenol and guanidine isothiocyanate. And furthermore, the open claim language (see above) allows for the inclusion of guanidine reagent in the lysis buffer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (J Clin Microbiol. 2000 Dec;38(12):4326-31) in view of Chomczynski

(U.S. 5,346,994), and in further view of Majumdar et al. (Biotechniques. 1991 Jul;11(1):94-101).

With regard to claims 1-3 and 8-14, Cook teaches methods of RNA isolation from biological specimens (pg. 4327, methods, col. 1, for example). Specifically, the reference teaches methods (pg. 4327, col. 1, RNA extraction from whole blood, for example) comprising: (a) contacting the biological specimen with an admixture of (i) a mono-phasic solution of phenol and guanidine isothiocyanate (pg. 4327, col. 1, RNA extraction from whole blood, 2nd solution, TRIZOL solution necessarily contains phenol and guanidine isothiocyanate, for example), and (ii) a lysis buffer under conditions and for a time appropriate to form a homogenate (pg. 4327, col. 1, RNA extraction from whole blood, 1st solution, CALTRIMOX solution necessarily contains a dispersing agent, i.e. detergent, for example); (b) admixing the homogenate with a water-immiscible organic solvent under conditions and for a time appropriate to form an aqueous phase and an organic phase (pg. 4327, col. 1, RNA extraction from whole blood, RNA was extracted by manufacture's instructions, for example); (c) contacting the aqueous phase with a C_1-C_4 lower alcohol under conditions and for a time to form a precipitated RNA (pg. 4327, col. 1, RNA extraction from whole blood, RNA was extracted by manufacture's instructions, for example); and (d) recovering the precipitated RNA (pg. 4327, col. 1, RNA extraction from whole blood, RNA was extracted by manufacture's instructions, for example).

With regard to the "admixture" of solutions (i) and (ii), Cook expressly teaches that the CALTRIMOX-TRIZOL method was performed on some samples without the two DEPC water washes (pg. 4327, col. 1, RNA extraction from whole blood, for example). Thus within these methods, a CALTRIMOX residue was present in the reaction vessel during the addition of TRIZOL reagent.

With regard to the "manufacturer's instructions" referenced by Cook (pg. 4327, TRIZOL from Life Technologies, reference 5, for example), the Office believes it is understood that such instructions included the steps of: 1) forming aqueous/organic phases; and 2) RNA precipitation w/ isopropanol to isolate RNA from the TRIZOL homogenate, as such steps were considered standard in the art at the time of invention; however, in order to provide a clear understanding of the grounds of rejection, the Chomczynski reference is provided to demonstrate such method steps as standard methodology within RNA TRIZOL-based isolation at the time of invention (see Chomcynski; col. 5-6, Example 2, chloroform and isopropanol, for example).

With regard to the above claims, the CALTRIMOX lysis buffer referenced by Cook does not appear to comprise a chelating agent (e.g. EDTA) as required by the claimed invention.

Majumdar provides a supportive disclosure that expressly teaches methods of bacterial RNA isolation that include an initial homogenization step that utilizes a lysis buffer comprising a dispersing agent (e.g. detergent) and a chelating agent (e.g. EDTA) (abstract; pg. 96-97, lysis of bacterial cells, TRITON-X100 and EDTA, for example). The reference expressly teaches EDTA as an essential reagent (pg. 99, col. 2), further

highlighting that the simple extraction methods are useful for obtaining good yields from large and small samples (pg. 100, col. 3). It is submitted that referring to EDTA as an essential reagent would not have been surprising to a skilled artisan at the time of invention given that EDTA was commonly known as a metal complexing agent, free metal ion activity being undesirable within isolated RNA solutions.

With regard to claims 4-7, Majumdar teaches mammalian and *C. vibrioforme* samples (pg. 96-97, for example).

Thus, in summary, it is first submitted that it would have been *prima facie* obvious to a skilled artisan at the time of invention to utilize steps (b) and (c) of the claimed method as demonstrated by Chomczynski in the methods of Cook since the prior art expressly demonstrates such steps as standard practice within TRIZOL-based isolation methods.

Furthermore, it would have been *prima facie* obvious to a skilled artisan at the time of invention to include a chelating agent (e.g. EDTA) within the lysis buffer of Cook since the prior art expressly demonstrates such a chemical as essential to providing good RNA yield. A skilled artisan would recognize the benefit of including such a chemical so as to form metal complexes thereby reducing free metal ion activity.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 571-272-8507. The examiner can normally be reached on Monday-Friday 7:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher M. Babic/
Patent Examiner
Art Unit 1637
Technology Center 1600